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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/738,808	12/15/2000	Joseph C. Salamone	P02389	2389

7590

07/31/2002

Robert B. Furr, Jr.
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EXAMINER

SOUBRA, IMAD

ART UNIT

PAPER NUMBER

1744

DATE MAILED: 07/31/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/738,808

Applicant(s)

SALAMONE ET AL.

Examiner

Imad Soubra

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7&9-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7&9-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 3, 5-6, 9-11 and 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Ellis et al '327. Ellis et al '327 teaches a method of treating contact lenses with a polyethylene oxide (PEO) which comprises PEO chains attached to a core, such as cellulose (column 2, lines 15-29). A cationic cellulose polymer is also present in solution in Ellis preferred embodiment (column 2, line 32). The two components complex with one another and strongly absorb to the lens surface (column 4, line 47). Ellis teaches the use of additives such as additional PEO-containing materials, additional cationic cellulose, and polyvinyl pyrrolidone (column 5, lines 50-65). The hard, rigid, and soft contact lenses, such as those made of silicone hydrogel, treated by the method of the invention have the ability to repel protein deposits (column 6, lines 1-25). While Ellis does not specifically teach that the lens of his method will inhibit the adhesion of bacteria to the surface of the medical device, it is Examiner's position that the treatment of similar surfaces with similar materials would inherently yields the same result. In addition, Ellis teaches the ability of the lenses of his invention to inhibit the deposition of protein on the surface of said lenses. Because bacteria

comprise proteins, Ellis method of deterring protein deposits would inherently deter bacteria deposits.

2. Claims 1-7 and 9-16 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Ellis'261. Ellis et al teach a contact lens solution for wetting, soaking, and lubricating contact lenses, particularly those carrying an ionic charge. The solution may contain a cationic polymer that interacts with an oppositely charged surface of a contact lens to provide long lasting lens wettability and a cushioning, lubricating effect (abstract). Additionally, the complex formed on the lens surface increases the hydrophilicity of the lens and inhibits the adhesion of proteins (paragraph spanning columns 1 and 2). Ellis teach a variety of methods of providing an ionic complex to the surface of a contact lens. Treatment of an anionic lens with a lens solution containing cationic cellulose yields the complex taught by Ellis (Examples V and X). While Ellis' 262 does not specifically teach that the lens of his method will inhibit the adhesion of bacteria to the surface of the medical device, it is Examiner's position that the treatment of similar surfaces with similar materials would inherently yield the same result. In addition, Ellis teaches the ability of the lenses of his invention to inhibit the deposition of protein on the surface of said lenses. Because bacteria comprise proteins, Ellis method of deterring protein deposits would inherently deter bacteria deposits. Further, the inhibition of bacteria is present only in the preamble of the claim and is not a limitation on the claim for those reasons outlined above. In regard to claim 2, Ellis teaches a method of treating the surface to render it anionic prior to contact with the cationic

polysaccharide (cellulose), such as by providing linking units on the surface.

Alternatively, Ellis teaches incorporation of anionic units into the lens substrate during manufacture so an intermediate treatment step is not needed to create an anionic substrate (Example X, line 49; col.3, lines 57-column 4, line 18). In regard to the ionic interactions of claim 7, the negative groups on the biomedical device of Ellis are derived from, for example, carboxylate groups on the surface (column 4, line 68). The positive groups on the cationic polysaccharide may be provided by salts of solfonium, phosphonium, or ammonium (column 3, lines 58-68. In regard to the hydrogen-bonding interactions of claims 9-12, Ellis teaches as an alternative method of treatment, treating a polyacid surface with a solution of hydrogen-bonding polymer or treating a hydrogen-bonding surface with a polyacid. Reactions occur through hydrogen bonding of hydrogen-bond accepting groups, such as pyrrolidone or PEO, with the surface (column 4, lines 18-27). The surface, as disclosed above, may contain carboxylate groups, which are hydrogen-donating. In regard to the covalent and hydrophobic interactions of claims 13 and 14, it is Examiner's position that these interactions are occurring inherently. The surface of the substrate of Ellis is hydrophobic, whereas the coating yields a hydrophilic surface. Hydrocarbon and other hydrophobic groups cluster in regions that exclude water. Therefore, the hydrophobic side groups present on the cellulose will automatically cluster at the surface of the hydrophobic substrate, while the hydrophilic groups will remain on the outermost region of the coating to be closest to the water in solution. Covalent bonding is also occurring in the numerous bonding techniques discussed by Ellis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ellis '327 or Ellis '261. Ellis '327 or Ellis '261 teaches that which is disclosed above, including the treatment of contact lenses, but fail to teach that the contact lens is an extended wear lens. It is Examiner's position that the generic teachings of Ellis '261 of a variety of contact lenses, such as those that can be worn for long periods of time would be inclusive of extended wear lenses. As for the Ellis '327 reference, the generic teachings of a variety of contact lenses, such as those that are hard, soft, or rigid, would be inclusive of extended wear lenses. Therefore, it would have been obvious of one having ordinary skill in the art at the time that the invention was made to use the method

of Ellis '327 and/or Ellis '261 for treating a variety of contact lenses, including those that are extended wear.

Response to Arguments

4. Applicant's arguments with respect to claims 1-7 and 9-19 have been considered but are moot in view of the new ground(s) of rejection.

5. The Examiner is aware of Application serial number 09/695529 ^{ABN} which appears the claims are very similar to the claims of this case. Applicant is required to furnish information regarding related and/or copending applications that have similar and/or the same claims.

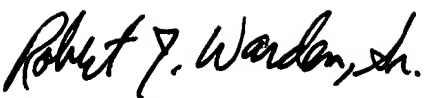
Conclusion

Any inquiry concerning this communication from the examiner should be directed to Imad Soubra whose telephone number is (703) 305-3541. The examiner can normally be reached on 8:30 am to 4:30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Warden can be reached on (703) 308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 879-9310 for regular communications and (703) 872-9311 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 306-5665.

Application/Control Number: 09/738,808
Art Unit: 1744

Page 7

Imad Soubra
July 25, 2002


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